

(19) World Intellectual Property Organization  
International Bureau



(43) International Publication Date  
6 March 2003 (06.03.2003)

PCT

(10) International Publication Number  
WO 03/017893 A1

(51) International Patent Classification<sup>7</sup>: A61F 5/03, 5/02

(21) International Application Number: PCT/IL02/00717

(22) International Filing Date: 29 August 2002 (29.08.2002)

(25) Filing Language: English

(26) Publication Language: English

(30) Priority Data:  
145205 30 August 2001 (30.08.2001) IL

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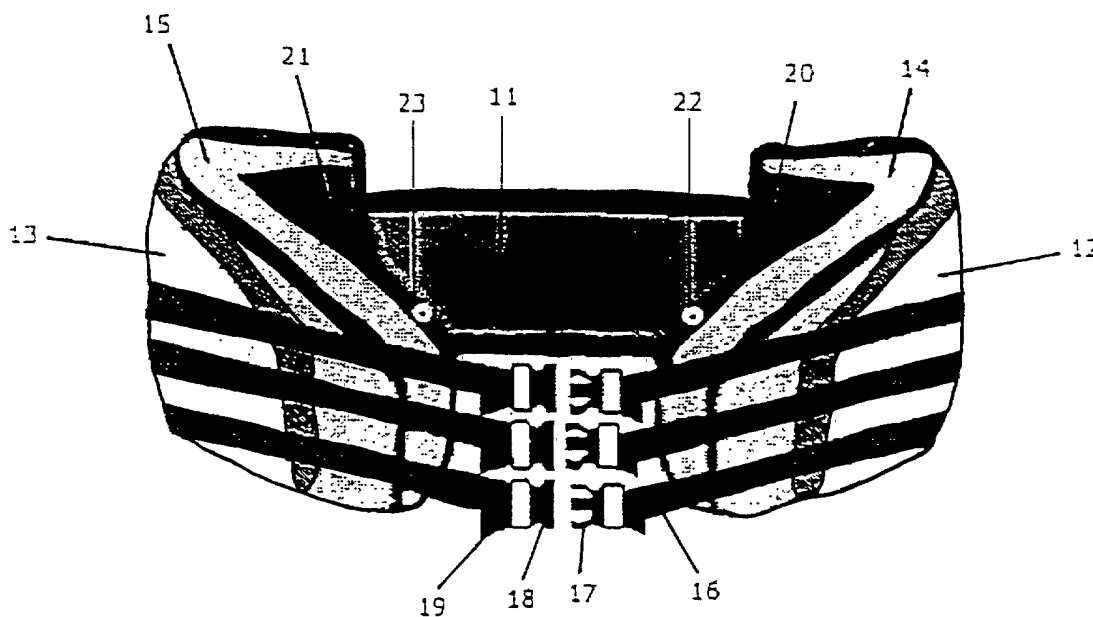
(81) Designated States (*national*): AE, AG, AL, AM, AT, AU, AZ, BA, BB, BG, BR, BY, BZ, CA, CH, CN, CO, CR, CU, CZ, DE, DK, DM, DZ, EC, EE, ES, FI, GB, GD, GE, GH, GM, HR, HU, ID, IL, IN, IS, JP, KE, KG, KP, KR, KZ, LC, LK, LR, LS, LT, LU, LV, MA, MD, MG, MK, MN, MW, MX, MZ, NO, NZ, OM, PH, PL, PT, RO, RU, SD, SE, SG, SI, SK, SL, TJ, TM, TN, TR, TT, TZ, UA, UG, US, UZ, VC, VN, YU, ZA, ZM, ZW.

(84) Designated States (*regional*): ARIPO patent (GH, GM, KE, LS, MW, MZ, SD, SL, SZ, TZ, UG, ZM, ZW), Eurasian patent (AM, AZ, BY, KG, KZ, MD, RU, TJ, TM), European patent (AT, BE, BG, CH, CY, CZ, DE, DK, EE, ES, FI, FR, GB, GR, IE, IT, LU, MC, NL, PT, SE, SK, TR), OAPI patent (BF, BJ, CF, CG, CI, CM, GA, GN, GQ, GW, ML, MR, NE, SN, TD, TG).

Published:  
— with international search report

For two-letter codes and other abbreviations, refer to the "Guidance Notes on Codes and Abbreviations" appearing at the beginning of each regular issue of the PCT Gazette.

(54) Title: PELVIC IMMOBILIZER



(57) Abstract: The present invention is primarily directed to a pelvic immobilizer comprising a wide band constructed of a material that is essentially non-elastic in a horizontal direction, characterized in that said wide band comprises a posterior portion that is continuous at its two ends with two lateral portions, wherein each of said lateral portions bears an anatomically-shaped cushion on its inner surface, said cushion approximating in size and shape to the human iliac wing, and wherein one or more connecting straps are attached to the exterior surface of each of said lateral portions, said connecting straps extending anteriorly and medially from the anterior free margin of each of said lateral portions.



WO 03/017893 A1

## PELVIC IMMOBILIZER

### Field of the Invention

The present invention relates to a device for use in immobilizing the pelvis in cases of traumatic and non-traumatic pelvic disorders. More specifically, the present invention discloses a device that provides pelvic stabilization in a non-invasive manner, and that may be used in both pre-hospital and hospital settings for pelvic fractures, and ambulatory and hospital use in cases of non-traumatic pelvic disorders such as symphysiolysis and sacroileitis.

### Background of the Invention

Pelvic trauma presents a particular set of challenges to the medical and paramedical team, in view of the need to provide both immediate stabilization of the skeletal structures and to arrest the profuse bleeding often associated with such conditions. A further complicating factor that frequently arises is the need to provide the initial treatment under difficult, non-hospital conditions, such as at the site of road-traffic accidents or on the battlefield. Moreover, by the very nature of the situations in which pelvic fracture occurs, the patient may often also be suffering from serious injury to other parts of the body, including fractures of the spinal column, cranium and limbs, each of which may be associated with serious or life-threatening soft-tissue damage and blood loss. Finally, there are other medical disorders, in which pelvic

-2-

instability causes discomfort, such as symphysiolysis and sacroileitis.

There is thus a need for a device for stabilizing pelvic fractures that may be easily, rapidly and comfortably applied to the patient in the field, and which can exert optimally-directed compressive forces sufficient to provide both stabilization of fractured bones and significant reduction in blood loss in pelvic trauma, as well as stabilization of the pelvic ring in other pelvic disorders such as symphysiolysis and sacroileitis in order to relieve pain.

The prior art has suggested several methods for stabilizing the pelvic ring structures in cases of trauma. These are essentially of two different types: external fixators comprising metal pins inserted into the iliac crest connected to an externally placed frame or clamp, and non-invasive devices for providing compression and/or stabilization of the fractured pelvis.

US 6,240,923 discloses a pelvic fracture immobilizer consisting of a wide band of firm material such as canvas and a plurality of straps, each having a ratcheting buckle. Compressive force is applied by wrapping the band around the affected area and closing and tightening the dynamic buckles.

WO9719658 discloses a device for stabilizing unstable pelvic fractures comprising a belt for fitting around the pelvis of a subject, means in connection with the belt for securing it in a tightened state against the victim of accident, and at least two first expandable means arranged so as to press against the posterior side of the pelvic ring opposite the pelvic sockets upon expansion and to further tighten the belt.

US6066109 describes a method for anatomical reduction of pelvic fractures involving the use of a narrow belt having at least two inflatable bladders slidably positionable along the belt. Operationally, the device is positioned to encircle the hips of a patient with a bladder positioned over each of the patient's hip bones. The belt is fastened in place by means of a clasp, and a pump is used to selectively inflate each of the bladders.

It is a purpose of the present invention to provide a non-invasive pelvic immobilization device for use in the management of pelvic trauma.

It is a further purpose of the invention to provide a pelvic immobilization device that may be easily and safely applied to the traumatized or otherwise structurally or functionally compromised pelvis of a subject in need of such treatment.

A further object of the invention is to provide a pelvic immobilization device of robust design that permits

movement of the patient under difficult circumstances (such as at accident sites and in the battlefield) without compromising the effectiveness of said device.

It is yet a further object of the invention that the device disclosed therein may be used at all stages of the management of pelvic trauma: from the accident site or battlefield to the hospital emergency room or operating suite.

It is yet a further object of the invention that the device disclosed therein will be used for stabilizing the pelvis in non-traumatic disorders such as symphysiolysis and sacroileitis.

A still further purpose of the invention is to provide a pelvic stabilization device that overcomes the problems and shortcomings of previous devices.

Further objects and advantages of the present invention will become apparent as the description proceeds.

#### **Summary of the Invention**

It has now been unexpectedly found that it is possible to provide stabilization and compression of the fractured or otherwise compromised pelvic ring, in hospital, pre-hospital and ambulatory settings, by means of an externally placed, non-invasive immobilization device, wherein the compressive forces are directed towards anatomically-relevant portions of said pelvic ring by means of

anatomically-shaped elements located within said device. The presence of these anatomically-shaped elements obviates the need for the use of delicate, easily-damaged components such as inflatable bags for providing the primary, directed compressive force on the traumatized or otherwise-compromised pelvis, thus permitting its effective use under field conditions. The ease of use afforded by these structural features also permits the effective use of the device of the present invention by non-specialist operators, such as paramedic and first-aid workers.

The present invention is primarily directed to a pelvic immobilizer comprising a wide band constructed of a material that is essentially non-elastic in a horizontal direction, characterized in that said wide band comprises a posterior portion that is continuous at its two ends with two lateral portions, wherein each of said lateral portions bears an anatomically-shaped cushion on its inner surface, said cushion approximating in size and shape to the human iliac wing, and wherein one or more connecting straps are attached to the exterior surface of each of said lateral portions, said connecting straps extending anteriorly and medially from the anterior free margin of each of said lateral portions.

The pelvic immobilizer device disclosed immediately hereinabove is intended for use in the stabilization and compression of pelvic fractures as well as to provide pelvic stabilization in non-traumatic conditions in which the pelvic ring may be structurally or functionally

compromised, such as symphysiolysis and sacroileitis, in which said stabilization would cause relief of pain and discomfort.

The term "iliac wing" as used hereinabove and hereinbelow, is used to describe the portion of the human ileum that is superior to the inferior gluteal line, including the iliac crest, iliac tuberosity and iliac fossa.

The term "anatomically-shaped cushion" as used herein, is intended to indicate a structural element constructed of a firm but deformable material (e.g. canvas), said element having a size and shape approximating to that of the human iliac wing.

In one preferred embodiment of the invention, up to three connecting straps are attached to each of the lateral portions.

In a preferred embodiment of the invention, each of the one or more connecting straps on one side of the immobilizer is fitted with the male half of a dynamic buckle, and wherein each of the connecting straps on the other side is fitted with the corresponding female half of said dynamic buckle.

In a preferred embodiment of the present invention, the pelvic fracture immobilizer further comprises a pair of pneumatic airbags, each of which is attached to the inner surface of one of the cushions.

-7-

In another preferred embodiment of the invention, the inner surface of each of the cushions is lined with a deformable material. In a more preferred embodiment, the deformable material is a silicon-based material.

In yet another preferred embodiment, the pelvic immobilizer may be fitted with a particularly delicate set of cushions for use in the management of symphysiolysis in pregnancy.

In another aspect, the present invention is also directed to a method for immobilizing the pelvis in a patient presenting with a traumatic or non-traumatic pelvic disorder, comprising wrapping a wide band around the pelvic region of a patient in need of such treatment, wherein said band bears a pair of anatomically-shaped cushions attached to the antero-lateral portions of its inner surface, and wherein said band is placed such that said cushions are located over the iliac wings, fastening said band in place by means of anteriorly connecting pairs of straps attached to the exterior surface of said band, said straps being fitted with means for dynamic tensioning, and applying the desired degree of tension by pulling the free ends of the connected straps through said dynamic tensioning means.

The term "desired degree of tension" refers to the amount of tension on the connecting straps that the operator determines to be necessary in order to produce the optimal compressive forces on the pelvic ring. Optimal compressive forces are those that provide maximum stabilization of the pelvic ring whilst causing minimal soft tissue trauma.



In a preferred embodiment of the method of the invention, the means for dynamic tensioning are dynamic buckles.

In another preferred embodiment, the method of the invention further comprises the controlled inflation of airbags that are attached to the inner surface of the anatomically-shaped cushions. The inflated airbags are of use *inter alia* in preventing the formation of decubitus ulcers, thus substantially prolonging the length of time in which the immobilizer may be comfortably used to periods of days and weeks.

In one preferred embodiment of the abovementioned method, the pelvic disorder is a traumatic pelvic disorder. In a particularly preferred embodiment, the traumatic pelvic disorder comprises one or more fractures of the pelvic ring.

In another preferred embodiment of the method of the invention, the pelvic disorder is a non-traumatic disorder. In one particularly preferred embodiment, the non-traumatic pelvic disorder is symphysiolysis. In another particularly preferred embodiment, the non-traumatic pelvic disorder is sacroileitis.

In another aspect, the pelvic immobilizer disclosed hereinabove is provided for use in the management of traumatic pelvic disorders. In a preferred embodiment, the traumatic pelvic disorder to be managed comprises one or more fractures of the pelvic ring.

The present invention also provides a pelvic immobilizer, as disclosed and described hereinabove, for use in the management of non-traumatic pelvic disorders. In one preferred embodiment of this aspect of the invention, the non-traumatic pelvic disorder to be managed is symphysiolysis. In another preferred embodiment, the non-traumatic pelvic disorder to be managed is sacroileitis.

All the above and other characteristics and advantages of the present invention will be further understood from the following illustrative and non-limitative examples of preferred embodiments thereof.

#### **Brief Description of the Drawings**

**Fig. 1** illustrates an anterior view of one embodiment of the device of the invention.

**Fig. 2** illustrates a posterior view of the device depicted in Fig. 1.

**Fig. 3** depicts an anterior view of a further embodiment of the device of the invention.

**Fig. 4** illustrates the pelvic immobilizing device of the invention in use.

### Detailed Description of Preferred Embodiments

Referring to Figs. 1 and 2, one embodiment of the pelvic immobilizer, indicated generally as **10**, comprises a wide posterior band **11** made of a material that is essentially non-elastic in a horizontal direction (e.g. canvas or a synthetic material such as Cordora), the lateral edges of which are connected to left and right lateral wing-shaped bands **12** and **13**. In cases in which the pelvic immobilizer is used in the management of non-traumatic conditions, its inner layer will be covered with a smooth fabric such as silk, thus enabling the use of said immobilizer for extended periods of time.

Said lateral bands **12** and **13** approximately conform in both size and shape to the pelvic iliac wings. Firm cushions **14** and **15** are attached to the inner surfaces of lateral bands **12** and **13**, respectively. Said cushions may be constructed of any suitable firm but resilient material, such as canvas, and are of a similar size and shape as lateral bands **12** and **13**, which as stated hereinabove, are designed to conform to the size and shape of the iliac wings.

By means of the anatomically-shaped cushions, the device, when in use, provides optimal compression of the pelvic ring. The attachment of cushions **14** and **15** to lateral bands **12** and **13** may be achieved by any suitable permanent means, including gluing, stapling and stitching, or by any suitable removable means, including the use of Velcro® tape. The use of removable attachment means such as

-11-

Velcro® tape is particularly advantageous, as it allows anterior-posterior re-positioning of the cushions in relation to the lateral bands, thus permitting the immobilizing device to be used with a wide range of different-sized pelvic rings. A plurality of connecting straps **16** are attached to the anterior surfaces of the lateral bands **12** and **13** in proximity to their free anterior margins. Straps **16** may be fitted with any suitable fasteners for ease of securing each strap with its contralateral counterpart. In the embodiment shown in Fig. 1, the fasteners are dynamic buckles, each of which consists of a male element **17** and a female element **18**. Each of the straps **16** has a free end **19** for the purposes of providing horizontally-directed tension in the device following closure of said dynamic buckles **17, 18**, each of which is fitted with a friction device to prevent slippage of the straps **16** therethrough.

Fig. 3 depicts an alternative embodiment of the device of the invention. In addition to all of the elements described hereinabove and illustrated in Figs. 1 and 2, this embodiment of the device also includes inflatable airbags **20** and **21** that are attached to the inner surface of each of the anatomically-shaped cushions **14** and **15**. The inflatable airbags may be made of any suitable material such as rubber, or any other airtight, deformable material, such as is well-known to the skilled artisan in the field.

Said airbags may be attached to the cushions by any suitable means, including, but not limited to gluing,

-12-

stitching, stapling and the use of Velcro® tape. Each of the airbags is provided with a one-way valve having an opening on the antero-superior surface thereof. These valves are shown in fig. 3 as valves **22** and **23**, and are used for inflating and deflating said airbags. Inflation may be performed by the use of any suitable inflating device, including manual pumps, pneumatic compressors, and mouth tubes. By means of inflating the airbags, fine adjustments may be made to the amount of compressive force applied to the pelvic structures. In addition, controlled inflation of the airbags may prevent damage to the skin and subcutaneous tissues by lowering pressure on said tissues over bony prominences. Moreover, use of the above-described controlled inflation of the airbags may assist in preventing the formation of decubitus ulcers, particularly when the immobilizer is to be used for prolonged periods of time.

Fig. 4 illustrates a pelvic immobilization device as disclosed and described hereinabove, in use on a subject. It may be seen from this figure that the lateral bands **12** and **13** and anatomically-shaped cushions **14** and **15** are positioned over the iliac wings, thus directing the compressive forces generated by the tensed connecting straps towards the largest elements of the bony pelvic ring, said elements (i.e. the iliac wings) being those that provide the largest contribution to the mechanical stability of the pelvis.

-13-

In order to use the immobilizing devices of invention, the device **10** is first wrapped around the pelvic region of the patient, ensuring that the anatomically-shaped cushions **14** and **15** are correctly placed over the iliac wings. The device is then loosely secured anteriorly by means of connecting each of the connecting straps **16** to its contralateral counterpart, by means of uniting the male and female halves **17** and **18** of the dynamic buckles. The desired compression of the traumatized or otherwise compromised pelvis is then achieved by sequentially tightening each connecting strap by means of pulling its free end **19**. In the preferred embodiment of the device of the invention illustrated in fig. 3 and described hereinabove, the degree of local pressure over the iliac wings may then be adjusted by controlled inflation of the airbags **20** and **21**, by way of valves **22** and **23**.

The robustness of the device coupled with its simplicity of use and lack of dependence on air pressure for its primary pressure-generating source facilitates its use under difficult situations such as on the battlefield or at the site of a road-traffic accident. Once applied to the patient as described hereinabove, the patient may then be moved to the hospital setting with the immobilizer securely in place. Visual and manual access to pelvic and lower abdominal structures (as may be required during ambulance transportation or in the hospital emergency room) may be gained by releasing the tension on one, and even two, of the connecting straps and opening the dynamic buckle attached thereto, without compromising the immobilizing

effect achieved by the device. In addition, all of the components of the device of the invention may be made of radiolucent materials, thus permitting the use of imaging techniques with the device *in situ*. These features thus permit the use of the immobilization device of the invention at all stages of management of pelvic trauma from the initial site of the accident to the operating table.

While specific embodiments of the invention have been described for the purpose of illustration, it will be understood that the invention may be carried out in practice by skilled persons with many modifications, variations and adaptations, without departing from its spirit or exceeding the scope of the claims.

Claims

1. A pelvic immobilizer comprising a wide band constructed of a material that is essentially non-elastic in a horizontal direction, characterized in that said wide band comprises a posterior portion that is continuous at its two ends with two lateral portions, wherein each of said lateral portions bears an anatomically-shaped cushion on its inner surface, said cushion approximating in size and shape to the human iliac wing, and wherein one or more connecting straps are attached to the exterior surface of each of said lateral portions, said connecting straps extending anteriorly and medially from the anterior free margin of each of said lateral portions.

2. A pelvic immobilizer according to claim 1, wherein up to three connecting straps are attached to each of the lateral portions.

3. A pelvic immobilizer according to claim 1, wherein each of the one or more connecting straps on one side of said immobilizer is fitted with the male half of a dynamic buckle, and wherein each of the connecting straps on the other side is fitted with the corresponding female half of said dynamic buckle.

4. A pelvic immobilizer according to claim 1, further comprising a pair of pneumatic airbags, each of which is attached to the inner surface of one of the cushions.



5. A pelvic immobilizer according to claim 1, wherein the inner surface of each of the cushions is lined with a deformable material.

6. A pelvic immobilizer according to claim 5, wherein the deformable material is a silicon-based material.

7. A method for immobilizing the pelvis in a patient presenting with a traumatic or non-traumatic pelvic disorder, comprising wrapping a wide band around the pelvic region of a patient in need of such treatment, wherein said band bears a pair of anatomically-shaped cushions attached to the antero-lateral portions of its inner surface, and wherein said band is placed such that said cushions are located over the iliac wings, fastening said band in place by means of anteriorly connecting pairs of straps attached to the exterior surface of said band, said straps being fitted with means for dynamic tensioning, and applying the desired degree of tension by pulling the free ends of the connected straps through said dynamic tensioning means.

8. A method according to claim 7, wherein the means for dynamic tensioning are dynamic buckles.

9. A method according to claim 7, further comprising the controlled inflation of airbags that are attached to the inner surface of the anatomically-shaped cushions.

10. A method according to any one of claims 7 to 9, wherein the pelvic disorder is a traumatic pelvic disorder.

11. A method according to claim 10, wherein the traumatic pelvic disorder comprises one or more fractures of the pelvic ring.

12. A method according to any one of claims 7 to 9, wherein the pelvic disorder is a non-traumatic pelvic disorder.

13. A method according to claim 12, wherein the non-traumatic pelvic disorder is symphysiolysis.

14. A method according to claim 12, wherein the non-traumatic pelvic disorder is sacroileitis.

15. A pelvic immobilizer according to claim 1 for use in the management of a traumatic pelvic disorder.

16. A pelvic immobilizer for use according to claim 15, wherein the traumatic pelvic disorder comprises one or more fractures of the pelvic ring.

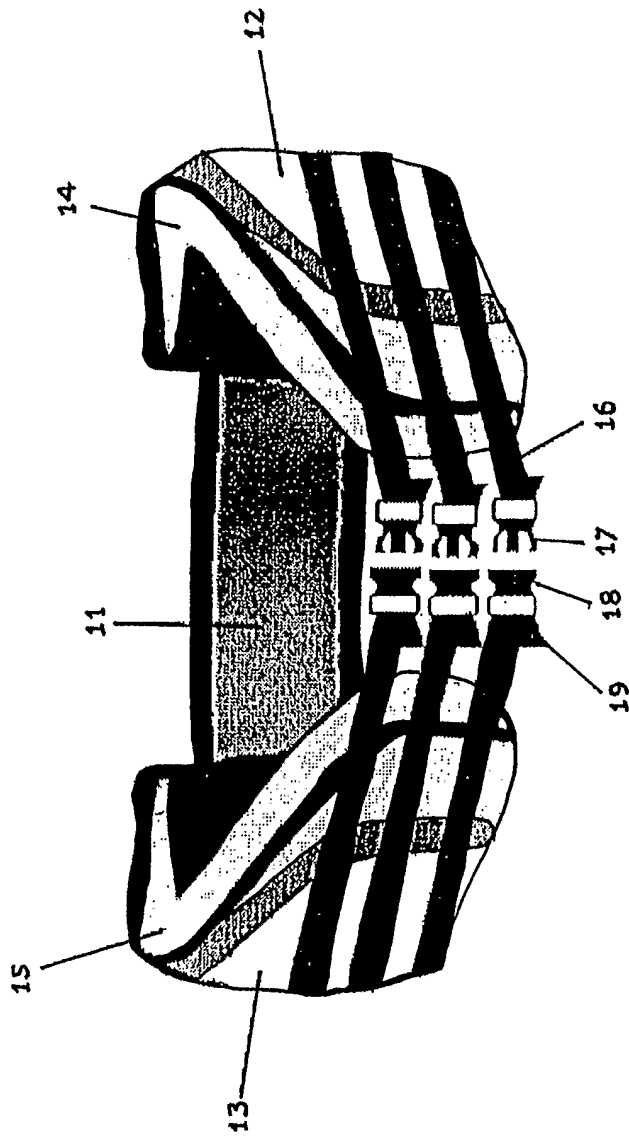
17. A pelvic immobilizer according to claim 1 for use in the management of a non-traumatic pelvic disorder.

18. A pelvic immobilizer for use according to claim 17, wherein the non-traumatic pelvic disorder is symphysiolysis.

19. A pelvic immobilizer for use according to claim 17, wherein the non-traumatic pelvic disorder is sacroileitis.

1/4

FIG 1



10

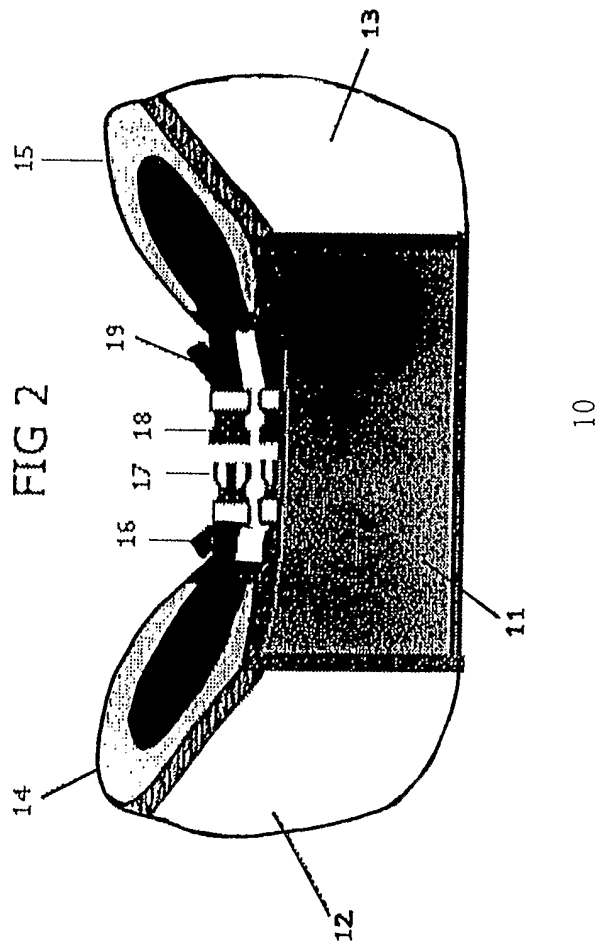
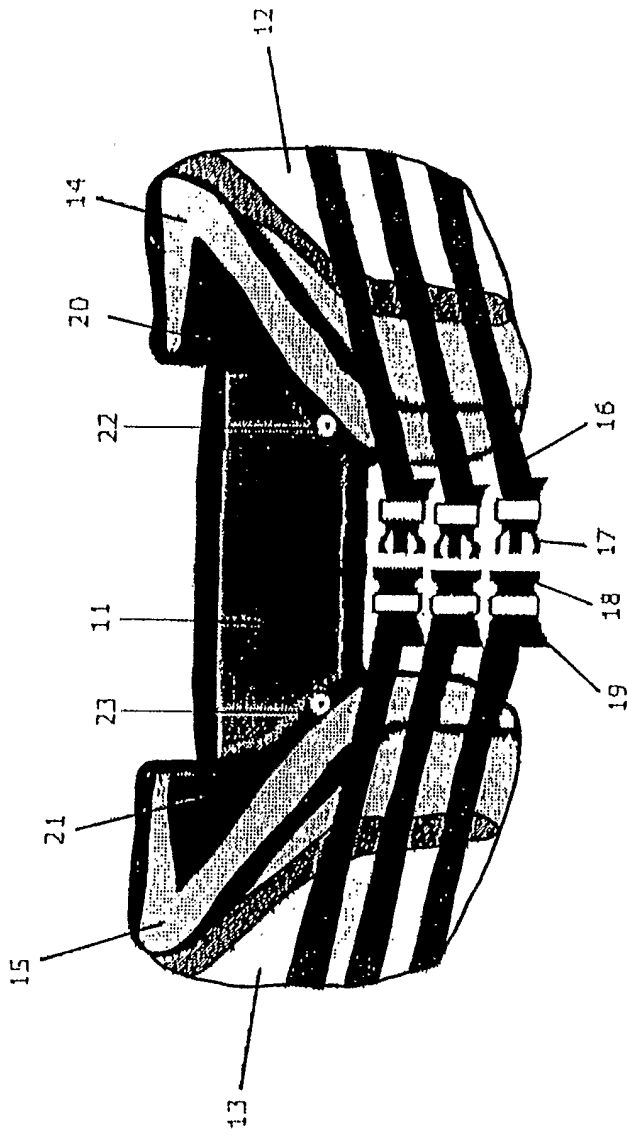


FIG 3



4/4

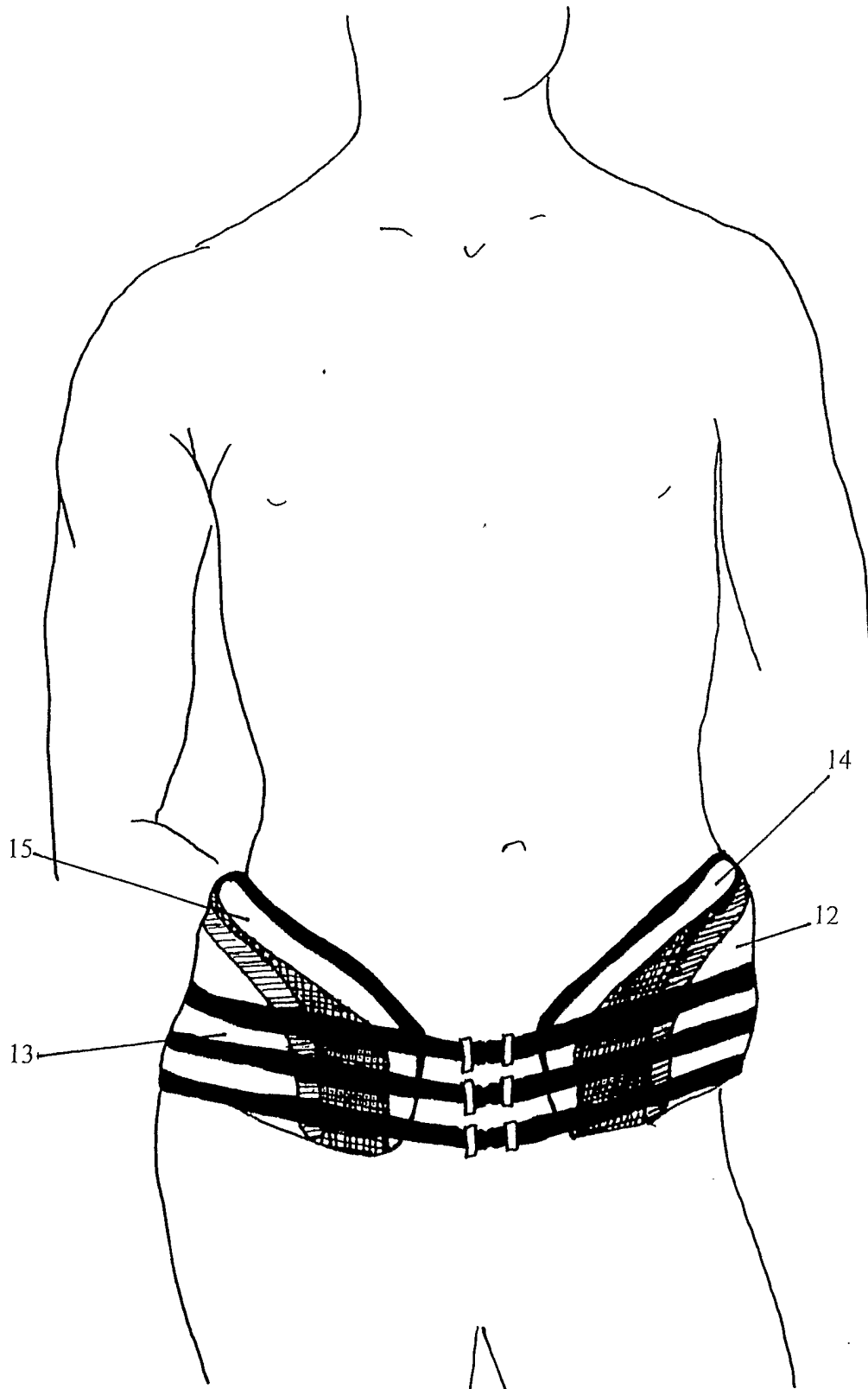


FIG 4

INTERNATIONAL SEARCH REPORT

In tional Application No  
PCT/IL 02/00717

A. CLASSIFICATION OF SUBJECT MATTER  
IPC 7 A61F5/03 A61F5/02

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)  
IPC 7 A61F A41D

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)

EPO-Internal

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category °	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X,P	WO 01 89433 A (UNIV NEW YORK) 29 November 2001 (2001-11-29) page 10, line 13 - line 27 page 13, line 12 - line 27 page 18, line 1 - line 15 figures 1,2,8	1-5, 15-19
X	US 6 066 109 A (BUSER BYRON MAXWELL ET AL) 23 May 2000 (2000-05-23)	1-3,5, 15-19
Y	column 3, line 1 - line 36 figure 2	6
Y	US 5 256 135 A (AVIHOD ELI) 26 October 1993 (1993-10-26) column 4, line 57 - line 67 figure 3	6
	-/--	

Further documents are listed in the continuation of box C.

Patent family members are listed in annex.

° Special categories of cited documents :

- \*A\* document defining the general state of the art which is not considered to be of particular relevance
- \*E\* earlier document but published on or after the international filing date
- \*L\* document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)
- \*O\* document referring to an oral disclosure, use, exhibition or other means
- \*P\* document published prior to the international filing date but later than the priority date claimed

- \*T\* later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention
- \*X\* document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone
- \*Y\* document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art.
- \*Z\* document member of the same patent family

Date of the actual completion of the international search

28 November 2002

Date of mailing of the international search report

06/12/2002

Name and mailing address of the ISA

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## INTERNATIONAL SEARCH REPORT

International Application No  
PCT/IL 02/00717

## C.(Continuation) DOCUMENTS CONSIDERED TO BE RELEVANT

Category °	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	US 6 240 923 B1 (BARRICK E FREDERICK) 5 June 2001 (2001-06-05) column 2, line 61 -column 4, line 55 figures 1-3 -----	1-3, 15-19
A	US 3 526 221 A (GARBER RICHARD D) 1 September 1970 (1970-09-01) column 3, line 23 -column 4, line 12 figures 1-3 -----	1,2, 15-19



# INTERNATIONAL SEARCH REPORT

International application No.  
PCT/IL 02/00717

## Box I Observations where certain claims were found unsearchable (Continuation of item 1 of first sheet)

This International Search Report has not been established in respect of certain claims under Article 17(2)(a) for the following reasons:

1.  Claims Nos.: 7-14  
because they relate to subject matter not required to be searched by this Authority, namely:  
Rule 39.1(iv) PCT - Method for treatment of the human or animal body by therapy
2.  Claims Nos.:  
because they relate to parts of the International Application that do not comply with the prescribed requirements to such an extent that no meaningful International Search can be carried out, specifically:
3.  Claims Nos.:  
because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a).

## Box II Observations where unity of invention is lacking (Continuation of item 2 of first sheet)

This International Searching Authority found multiple inventions in this international application, as follows:

1.  As all required additional search fees were timely paid by the applicant, this International Search Report covers all searchable claims.
2.  As all searchable claims could be searched without effort justifying an additional fee, this Authority did not invite payment of any additional fee.
3.  As only some of the required additional search fees were timely paid by the applicant, this International Search Report covers only those claims for which fees were paid, specifically claims Nos.:
4.  No required additional search fees were timely paid by the applicant. Consequently, this International Search Report is restricted to the invention first mentioned in the claims; it is covered by claims Nos.:

### Remark on Protest

- The additional search fees were accompanied by the applicant's protest.
- No protest accompanied the payment of additional search fees.

INTERNATIONAL SEARCH REPORT

Information on patent family members

International Application No  
PCT/IL 02/00717

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